K123300

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JAN 18 2013

BD
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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date of Summary Preparation: November 08, 2012

1. **Submitted By:**

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Staff Regulatory Affairs Specialist

Becton, Dickinson and Company
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Franklin Lakes, NJ 07417

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2. **Device Name:**

Trade Name:	BD 31G and 32G Extra Thin Wall (XTW) Pen Needles with PentaPoint™
Common Names:	Insulin Pen Needle
Classification Name:	Needle, Hypodermic, Single Lumen
Classification:	Class II, 21 CFR 880.5570 FMI

3. **Predicate Device:**
BD Pen Needle- K100005 and K051899
Manufactured by: Becton, Dickinson and Company

4. **Device Description:**

BD pen needles are single use, sterile, medical devices designed to be used in conjunction with pen injectors and pen cartridges. Pen needles are used by consumers, caregivers and health care professionals. They are offered in various gauge sizes (29G, 30G, 31G and 32G) and lengths (4mm, 5mm, 8mm and 12.7mm). BD Pen Needles are sterile (gamma irradiation sterilization), non-toxic and non-pyrogenic.

The pen needle assembly consists of a doubled-ended cannula that is assembled into an injection-molded hub using adhesive. The hub has internal threads, which allow it to be screwed onto the pen-injector device. This allows the Non Patient (NP) end of the cannula to penetrate through the rubber septum of the cartridge. The Patient end and NP end of the cannula are lubricated using silicone based lubes for ease of injection and rubber septum penetration. An injection-molded inner shield is assembled over the Patient end of the Cannula to protect the point from damage and accidental needle-sticks. This needle assembly is inserted into a protective injection-molded outer cover and sealed with a peel-away (tear drop) label to provide sterile barrier and tamper evidence. The outer cover is also used to remove the hub and cannula from the pen. The peel-away label is pre-printed with information, which includes the lot number and needle gauge / length. The individual needle assemblies are packaged in polybags and / or cartons, and placed into shippers with appropriate labeling. The shipper cases are palletized and sterilized to an SAL 10^{-6} by gamma irradiation.

The purpose of this Special 510(k) is to expand the needle range to include the 31G and 32G Extra Thin Wall (XTW) pen needles with PentaPoint™ design. The intended use for the modified device remains the same as the predicate devices.

Also it is BD's intent to notify the Agency of a non-significant change to the cannula point bevel geometry from 3 bevels to 5 bevels (PentaPoint™).

5. **Statement of Intended Use/Indications for Use:**

BD Pen Needle is intended for use with pen injector device for subcutaneous injection of drugs, including insulin and exenatide.

6. **Technological Characteristics:**

The principal device of this premarket notification is the result of a design change to the predicate devices conducted in accordance with Quality System Regulations. The BD 31G and 32G XTW Pen Needle with PentaPoint™, modified, is equivalent to the predicate devices, given that:

- Has the same intended use and indications for use as the predicate devices

- Uses the same operating principles
- Incorporates the same basic design
- Is manufactured from the same materials
- Is sterilized using the same mode
- Is sterilized with SAL of 10^{-6}
- Is packaged using same unit and case materials
- Same fundamental scientific technology

The only design differences between the modified BD 31G and 32G XTW Pen Needles with PentaPoint™ and the predicate devices are the inner diameter and needle point.

7. **Performance:**

Bench tests relating to the performance of the BD 31G and 32G XTW Pen Needle with PentaPoint™ were conducted.
The principal device demonstrated equivalent performance to the predicate devices during bench testing. Bench testing consisted of:

Tubing diameters	Per ISO 11608-2, section 4.3.1 (tubing dimensions meet OD and ID requirement).
Patency of lumen	Per ISO 11608-2, section 4.4 (stylet, having a diameter equivalent to 80% ±2% of lumen ID passes through freely).
Needle points	Per ISO 11608-2, section 4.5 (visually sharp at 2.5X magnification, designed to minimize coring and fragmentation).
Type A Needle (length)	Per ISO 11608-2, section 4.3.2 (patient end within indicated length ± 1.25 mm)
Cannula load test (No pre-conditioning)	Per ISO 11608-2, section 4.9 and 9. ISO 7864 Section 13.1(cannula holds force of 22N for 5 seconds).
Cannula load test (with pre-conditioning)	Per ISO 11608-2, section 4.9 and 9. ISO 7864 section 13(cannula holds force of 22N for 5 seconds).
Lubrication	Per ISO 11608-2, section 4.7 (no visible droplets inside/outside surfaces of cannula).
Compatibility Testing	Per ISO 11608-2, section 4.10 (connectivity (torque).
Penetration Testing	Per BD Test Method TP700279

8. **Substantial Equivalence:**

The vast similarities of the BD 31G and 32G XTW Pen Needles with PentaPoint™ to the predicate devices support the substantial equivalence in intended use, function and basic composition. The testing to voluntary standards, ISO 11608-2 and ISO 7864 provides additional evidence that the BD 31G and 32G XTW Pen Needles with PentaPoint™ is substantially equivalent to the predicate devices in terms of safety, efficacy and performance.

The differences between the BD 31G and 32G XTW Pen Needles with PentaPoint™ and the predicate devices do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 18, 2013

Becton Dickinson & Company
Ms. Pasquale Amato
BD Medical Diabetes Care
1 Becton Drive
MC 372
Franklin Lakes NJ 07417-1880

Re: K123300
Trade/Device Name: BD 31G and 32G XTW Pen Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: December 18, 2012
Received: December 19, 2012

Dear Ms. Amato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

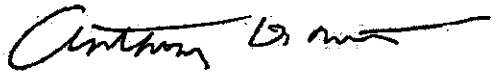
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123300

Device Name: BD 31G and 32G XTW Pen Needles

Indications For Use:

BD Pen Needle is intended for use with pen injector device for subcutaneous injection of drugs, including insulin and exenatide.

Prescription Use _____ AND/OR Over-The-Counter Use ___X_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Rick Chapman Date: 2013.01.18 14:27:04 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123300